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**510(k) SUMMARY**

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In accordance with the provisions of the Safe Medical Device Act of 1990, Nexsys, Inc., dba Medweb, LLC, is providing a summary of safety and effectiveness information regarding the Advanced 3D Web PACS™, Picture Archiving and Communications System.

**1.1 Company Identification**

Establishment Registration: 2953193  
Owner Operator Number: 9017001  
Nexsys Electronics, Inc. dba Medweb LLC  
667 Folsom St.  
San Francisco CA 94107  
Contact: Florent Saint-Elair  
Tel: (415) 541-9980  
Fax: (510) 276-2648

DEC 12 2006

**1.2 Official Correspondent**

Gary J. Allsebrook, Consultant  
Regulatory Management Services  
16303 Panoramic Way  
San Leandro CA USA 94578-1116  
Tel/fax: (510) 276-2648  
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Email: [regman10@comcast.net](mailto:regman10@comcast.net)

**1.3 Date of Submission**

November 28, 2006

**1.4 Device Name**

Classification Name:	PACS
Common/Usual Name:	Soft-copy reading and acquisition system
Proprietary Name:	Advanced 3D Web PACS™

**1.5 Substantial Equivalence**

Advanced 3D Web PACS™ has indications for use and a target population similar to other medical image management devices, including AccuImage, AccuView, (K990241), Neo Imagery Technologies, Insight Diagnostic Imaging Workstation (K982535) and Picker, Voxel Q™ and Voyager™ (K962010). All of

the functions that Advanced 3D Web PACS™ performs are available in at least one of the listed substantially equivalent devices. In most cases, the function is available in all of them. There are no significant differences between Advanced 3D Web PACS™ and the collective functions of all the predicate devices.

## **1.6 Device Description and Intended Use**

Advanced 3D Web PACS™ is a PACS system, comprised of acquisition components (Medweb secure DICOM Proxy Web Server, ), a central system manager component (Medical Transcription Server), a diagnostic workstation component (Radiologist Dashboard©), and an archiving component (DICOM Archive). The data flow is such that patient and procedure information is optionally delivered to the central system manager, followed by the acquisition of the image objects directly from the image sources or by one of the acquisition components. After receiving the procedure information or after receiving image objects, the central system manager searches for and retrieves relevant prior procedure data from the archive component. When the central system manager registers the acquired image objects and the retrieved prior procedure data, a user can access the information by selecting the item from the operator work list. The image data is transmitted to and rendered on the user's workstation using the diagnostic workstation components. After using the workstation to view the images, the user optionally dictates a report into the system, after which, a user can play back the dictation and transcribe it to text. Once Advanced 3D Web PACS™ central system manager registers a report, the report is available for access by the referring physician, or it can be exported into an information system. At some configured point in time, the image data and the report information is delivered to the archiving component for backup and long-term storage.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA

Advanced 3D Web PACS™ is a PACS and teleradiology system used to receive DICOM images, scheduling information and textual reports, organize and store them in an internal format, and to make that information available across a network via web and customized user interfaces. Advanced 3D Web PACS™ is for hospitals, imaging centers, radiologist reading practices and any user who requires and is granted access to patient image, demographic and report information.

## **1.7 Software Development**

Nexsys Electronics, Inc, dba Medweb LLC certifies that the Advanced 3D Web PACS™ software is designed, developed, tested and validated according to written procedures. These procedures identify individuals within the organization

responsible for developing and approving product specifications, coding and testing, validation testing and field maintenance. The software developed for this product is used to provide diagnostic quality images and associated information for the intended users.

## **1.8 Safety and Effectiveness**

### **General Safety and Effectiveness Concerns:**

The device labeling contains instructions for use and any warnings or cautions to provide for the safe and effective use of the device. It is the user's responsibility to insure that display quality, environmental lighting and other possible distractions are consistent with a clinical environment. . Advanced 3D Web PACS™ is a software application(s) device. The hardware components specified are all "off the shelf" computer components.

It is our conclusion that there is no software (or hardware component in the Advanced 3D Web PACS™ device, which would be used in conjunction with the Advanced 3D Web PACS™ device) that we know of, whose failure or latent design flaw would be expected to result in death or injury to a patient. Thus the "level of concern" on the Advanced 3D Web PACS™ device is "minor".

### **Substantial Equivalence Summary:**

Advanced 3D Web PACS™ is substantially equivalent in design and intended use(s) to diagnostic workstations, PACS and image management systems and substantiated in the substantial equivalence comparison chart in Tab 8. Any differences between the Advanced 3D Web PACS™ and the predicate devices have no significant influence on safety and effectiveness. Advanced 3D Web PACS™ , therefore, raises no new issues of safety or effectiveness from the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

Nexsys Electronics, Inc. dba Medweb LLC  
% Mr. Gary J. Allsebrook  
Consultant  
Regulatory Management Services  
16303 Panoramic Way  
SAN LEANDRO CA 94578-1116

DEC 12 2006

Re: K063221

Trade/Device Name: Nexsys, dba Medweb, LLC Advanced 3D Web PACS™ Picture Archiving and Communications System

Regulation Number: 21 CFR 892.2050

Regulation Name: Picture archiving and communications system

Regulatory Class: II

Product Code: LLZ

Dated: October 20, 2006

Received: October 24, 2006

Dear Mr. Allsebrook:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



*Protecting and Promoting Public Health*

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

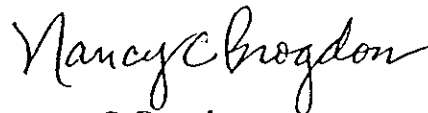
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): **K063221**

Device Name: Nexsys, dba Medweb, LLC, **Advanced 3D Web PACS™**  
Picture Archiving and Communications System

Indications For Use:

Advanced 3D Web PACS™ is a PACS and teleradiology system used to receive DICOM and other medical images, scheduling information and textual reports, organize and store them in an internal format, and to make that information available across a network via web and customized user interfaces. Advanced 3D Web PACS™ is for hospitals, imaging centers, radiologist reading practices and any user who requires and is granted access to patient image, demographic and report information.

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PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 901.109)

OR

Over-the-Counter Use \_\_\_\_\_

David R. Leggett (Optional Format 1-2-96)  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K063221